

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

Patrick et al.,

Plaintiffs,

v.

Civil Action No. 08-1025

FirstEnergy Generation Corp.,

Defendant.

Price et al.,

Plaintiffs,

v.

Civil Action No. 08-1030

FirstEnergy Generation Corp.,

Defendant.

MEMORANDUM OPINION

CONTI, Chief District Judge

I. Introduction

Before the court are expert challenges in two cases consolidated for discovery, *Patrick v. FirstEnergy Generation Corp.* (No. 08-1025) and *Price v. FirstEnergy Generation Corp.* (No. 08-1030).¹ These cases involve the Bruce Mansfield Power Plant (“Bruce Mansfield”), a coal-fired electric generating facility located along the Ohio River in Shippingport, Pennsylvania. Bruce Mansfield is owned and operated by defendant FirstEnergy Generation Corporation (“FirstEnergy” or “defendant”). The plaintiffs allege harm from air pollution discharged by Bruce Mansfield. The alleged pollution came in the form of “white rain,” a chronically discharged corrosive material, and “black rain,” a dark-colored sooty residue discharged on two occasions in 2006 and 2007. The white rain and black rain were deposited on the area surrounding Bruce Mansfield, allegedly causing property damage and adverse health effects. Plaintiffs also

¹ A third case consolidated for discovery purposes, *Hartle v. FirstEnergy Generation Corp.* (No. 08-1019), is not at issue in the present opinion.

allege harm from particulate matter emitted by Bruce Mansfield. The named plaintiffs in *Patrick* are four couples who make class-action claims for damages due to diminution of property value and for the cost of a health assessment or health effects study. The plaintiffs also seek to enjoin the plant from operating until it can prevent the white rain emissions. In *Price*, nineteen plaintiffs seek injunctive relief and monetary damages for adverse health effects and property damage.

The parties conducted extensive fact and expert discovery in these cases. Defendant filed motions to limit or preclude the testimony of twelve of plaintiffs' experts. Plaintiffs filed motions to limit or preclude the testimony of seven of defendant's experts. This memorandum opinion addresses defendant's motions to exclude the expert testimony of James S. Smith, PhD ("Smith") and Marilyn Howarth, MD ("Howarth").² The motions are fully briefed, and the court heard argument on February 4, 2014.

II. Legal Standards

Federal Rule of Evidence 702 governs the admissibility of expert testimony and states:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and

² The motions to exclude the testimony of Smith are ECF No. 187 (*Patrick*), and ECF No. 127 (*Price*). The motions to exclude the testimony of Howarth are ECF No. 184 (*Patrick*), and ECF No. 118 (*Price*). Unless otherwise noted, ECF numbers appearing in the text of this opinion refer to the *Patrick* case, No. 08-1025.

- (d) the expert has reliably applied the principles and methods to the facts of the case.

FED. R. EVID. 702. Under the seminal case of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), district courts must act as gatekeepers to “ensure that any and all scientific testimony or evidence admitted is ... reliable.”³ *Id.* at 589. The United States Court of Appeals for the Third Circuit explained that Rule 702 “embodies a trilogy of restrictions” that expert testimony must meet for admissibility: qualification, reliability and fit. *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003). The party offering the expert testimony has the burden of establishing each of these requirements by a preponderance of the evidence. *In re TMI Litig.*, 193 F.3d 613, 663 (3d Cir. 1999).

A. Qualification

An expert witness’s qualification stems from his or her “knowledge, skill, experience, training, or education.” FED. R. EVID. 702. The witness therefore must have “specialized expertise.” *Schneider*, 320 F.3d at 404. The court of appeals interprets the qualification requirement “‘liberally,’ holding that ‘a broad range of knowledge, skills, and training qualify an expert as such.’” *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 321 (3d Cir. 2003) (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994)). When evaluating an expert’s qualifications, district courts should not insist on a certain kind of degree or background. *Robinson v. Hartzell Propeller Inc.*, 326 F. Supp. 2d 631, 667 (E.D. Pa. 2004). An expert’s qualifications are determined with respect to each matter addressed in the proposed testimony. *Calhoun*, 350 F.3d at 322 (“An expert may be generally qualified but may lack qualifications to testify outside his area of expertise.”). “While the background,

3 While *Daubert* applied exclusively to scientific testimony, see *Daubert*, 509 U.S. at 590 n.8, the Supreme Court subsequently extended the district court’s gatekeeper function to all expert testimony. *Kuhmo Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999).

education, and training may provide an expert with general knowledge to testify about general matters, more specific knowledge is required to support more specific opinions.” *Id.*

B. Reliability

In *Daubert*, the Supreme Court stated that the district court’s gatekeeper role requires “a preliminary assessment of whether the reasoning or methodology underlying the testimony is ... valid and of whether the reasoning or methodology properly can be applied to the facts in issue.” *Daubert*, 509 U.S. at 592–93. The Court of Appeals for the Third Circuit enumerated the following eight factors that a district court may examine:

1. whether a method consists of a testable hypothesis;
2. whether the method has been subjected to peer review;
3. the known or potential rate of error;
4. the existence and maintenance of standards controlling the technique’s operation;
5. whether the method is generally accepted;
6. the relationship of the technique to methods which have been established to be reliable;
7. the qualifications of the expert witness testifying based on the methodology; and
8. the non-judicial uses to which the method has been put.

In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 742 n.8 (3d Cir. 1994) (“*Paoli II*”). This list of factors is a “convenient starting point,” but is “neither exhaustive nor applicable in every case.” *Kannankeril v. Terminix Int’l, Inc.*, 128 F.3d 802, 806–07 (3d Cir. 1997).

Under these factors, experts are not permitted to engage in a “haphazard, intuitive inquiry,” but must explain the research and methodology they employed in sufficient detail in order to allow the other party’s expert to test that hypothesis. *Oddi v. Ford Motor Co.*, 234 F.3d 136, 156 (3d Cir. 2000). Where an expert fails to use standards to control his or her analysis, “no ‘gatekeeper’ can assess the relationship of

[the expert's] method to other methods known to be reliable and the non-judicial uses to which it has been put.” *Id.* at 158.

“The evidentiary requirement of reliability is lower than the merits standard of correctness.” *Paoli II*, 35 F.3d at 744. “As long as an expert’s scientific testimony rests upon good grounds, based on what is known, it should be tested by the adversary process—competing expert testimony and active cross-examination—rather than excluded from jurors’ scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies.” *United States v. Mitchell*, 365 F.3d 215, 244 (3d Cir. 2004) (quoting *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998) (internal quotation marks omitted)).

C. Fit

The Rule 702 requirement that testimony “help the trier of fact to understand the evidence or to determine a fact in issue” is called the “fit” requirement. Fit requires a “connection between the scientific research or test result to be presented and particular disputed factual issues in the case.” *Paoli II*, 35 F.3d at 743 (quoting *United States v. Downing*, 753 F.2d 1224, 1237 (3d Cir. 1985)). “Fit’ is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes.” *Daubert*, 509 U.S. at 591. The standard for fit is “not that high,” although it is “higher than bare relevance.” *Paoli II*, 35 F.3d at 745.

III. Discussion

A. Defendant’s Motions to Limit the Testimony of Smith

Smith, a toxicologist, submitted an expert report entitled “Preliminary Characterization of Human Health Risk at Receptor Locations Potentially Impacted by Emmissions [sic] from the Bruce Mansfield Power Plant Located in Shippingport, Pennsylvania” (“Smith Rep.”).⁴ Smith opined that “[s]ufficient information exists to warrant additional and complete sampling and analysis of environmental media for

⁴ Smith submitted a separate report and different opinions in the *Hartle* case.

the purpose of determining the potential health risk posed by Bruce Mansfield Plant (BMP) emissions to people living in the vicinity of the facility.” (Smith Rep. 3, ECF No. 190-1.) This opinion is directed toward the *Patrick* plaintiffs’ claim under the Pennsylvania Hazardous Sites Cleanup Act (“HSCA”), 35 PA. STAT. §§ 6020.101–.1305, which provides for the cost of a health assessment study to be borne by a defendant “who is responsible for a release or threatened release of a hazardous substance from a site as specified in section 701.” *Id.* § 6020.702(a). That person

is strictly liable for the following response costs and damages which result from the release or threatened release or to which the release or threatened release significantly contributes: ... (3) Other reasonable and necessary or appropriate costs of response incurred by any ... person. ... (5) The cost of a health assessment or health effects study.

Id. Defendant challenges Smith’s opinion that a health assessment study is warranted on fit and reliability grounds.

1. Fit

Defendant asserts that there is a “threshold issue” about what a plaintiff must prove to be entitled to a health study. (Hr’g Tr. 5:17–23, Feb. 4, 2014, ECF No. 277.) Defendant points out that no case law directly establishes a standard for the imposition of a health study under the HSCA, and argues that, under any standard, plaintiffs must tie the risk or increased risk to Bruce Mansfield. (*Id.* at 5:24–6:9.) Since Smith did not opine that Bruce Mansfield was the cause of the increased risk, defendant argues his opinion does not fit or have any relevance. (*Id.* at 9:23–10:1.)

Like the parties, the court is aware of no decision addressing the standard applicable to determining whether a health effects study under the HSCA is warranted. The Pennsylvania Supreme Court addressed a medical monitoring claim, which it found cognizable under the terms “cost of response,” “health assessment,” and “health effects study” in section 6020.702(a) of the HSCA. *Redland Soccer Club, Inc. v.*

Dep't of the Army, 696 A.2d 137, 142 (Pa. 1997). The court held that in order to prevail on a claim for medical monitoring, a plaintiff must prove:

- (1) exposure greater than normal background levels;
- (2) to a proven hazardous substance;
- (3) caused by the defendant's negligence;
- (4) as a proximate result of the exposure, plaintiff has a significantly increased risk of contracting a serious latent disease;
- (5) a monitoring procedure exists that makes the early detection of the disease possible;
- (6) the prescribed monitoring regime is different from that normally recommended in the absence of the exposure; and
- (7) the prescribed monitoring regime is reasonably necessary according to contemporary scientific principles.

Id. at 145–46. Some of these elements obviously do not apply to a claim for a health effects study. The nature of a medical monitoring claim is sufficiently similar to a claim for a health assessment or health effects study to make the elements of a medical monitoring claim helpful in assessing a claim for a health assessment or health effects study. The first three medical monitoring elements from *Redland Soccer* are directly applicable to a claim for a health assessment or health effects study: (1) exposure greater than normal background levels; (2) to a proven hazardous substance; and (3) caused by the defendant's negligence. The sixth element is not relevant. Elements four, five, and seven would need to be modified as follows: (4) as a proximate result of the exposure, plaintiff has a significantly increased risk of contracting a serious disease, latent or otherwise; (5) a health assessment or health effects study procedure exists that makes screening for such a disease possible; and (6) the prescribed health assessment or health effects study is reasonably necessary according to contemporary scientific principles. These six elements will be used by

the court to conduct a *Daubert* analysis of the expert opinions about a health assessment or health effects study claim.

While Smith's testimony does not link the increased risk of harm to defendant's conduct (Smith Rebuttal Rep. 7, ECF No. 190-2), the opinions of plaintiffs' experts Ronald Petersen ("Petersen") and Gary Brown ("Brown"), found by the court to satisfy the requirements of Rule 702, connect Bruce Mansfield to hazardous substances on plaintiffs' properties. Based upon those expert reports, Howarth opined about the increased risk due to Bruce Mansfield emissions. Smith's testimony is relevant to whether a health effects study is reasonably necessary according to contemporary scientific principles. This relevancy is sufficient to satisfy the fit requirement of Rule 702 and *Daubert*. Defendant argues that none of plaintiffs' other expert witness can "fill in [the] gap" regarding causation. (Hr'g Tr. 8:17–9:2, Feb. 4, 2014, ECF No. 277.) The fact finder⁵ will determine whether the testimony of Petersen, Brown, and Howarth and the other evidence of record establish causation. If causation is established, Smith's testimony about the scientific necessity for a health assessment would be relevant and helpful. Smith's expert testimony will not be excluded on fit grounds.

5 The court is uncertain whether the imposition of a health assessment or health effects study is a matter for a jury or the court to determine. In *Redland Soccer*, the Pennsylvania Supreme Court considered medical monitoring as a form of equitable relief. 696 A.2d at 142. The plaintiffs in that case specifically identified the claim as equitable. *Id.* In *In re Paoli Railroad Yard PCB Litigation*, 916 F.2d 829, 851 (3d Cir. 1990) ("*Paoli I*"), cited with approval by the Pennsylvania Supreme Court, the Court of Appeals for the Third Circuit discussed a common law medical monitoring claim as a jury question: "[T]he issue for the jury is the less conjectural question of whether the plaintiff needs medical surveillance." The court will require additional briefing before deciding this issue. If the imposition of a health assessment is a jury question, the court will give a limiting instruction that Smith's testimony is not evidence of causation. If this question is one for the court, the court may hear Smith's testimony outside the presence of the jury, or, if a special jury interrogative is appropriate, the court will give a limiting instruction.

2. Reliability

Defendant raises a number of arguments about the reliability of Smith's preliminary risk characterization opinion: (1) Smith's opinion lacks the requisite certainty to be admissible; (2) Smith used an unreliable health standard for arsenic; (3) Smith performed a faulty analysis of the cancer risk from metals in soil; and (4) Smith's opinion regarding a statistical association between black rain and inhalation risk is invalid.⁶

Defendant challenges the "preliminary" nature of Smith's opinion. (ECF No. 188, at 2.) Defendant asserts that "[e]ven when done correctly, a preliminary risk assessment does not provide proof of increased risk or an actual injury in the context of a toxic tort claim." (*Id.* at 4.) Plaintiffs do not contest this. Plaintiffs are not offering Smith to opine about causation (which would be elements one through three discussed above); Smith is opining about whether a health assessment or health effects study should be ordered. (Hr'g Tr. 3:2–8, Feb. 4, 2014, ECF No. 277.) In light of this limitation, the court concludes that Smith's failure to definitively link Bruce Mansfield to any harm to plaintiffs does not render his opinion about the necessity of a health assessment or health effects study inadmissible.

Smith compared Petersen's predicted breathing zone arsenic levels to the California Environmental Protection Agency reference exposure level ("California REL") for acute exposure, 0.2 micrograms per cubic meter (" $\mu\text{m}/\text{m}^3$ "). (Smith Rep. 10, ECF No. 190-1.) Defendant argues that the California REL is an unreliable and inappropriate standard because it "is a conservative, health protective regulatory guideline, not an exposure level above which significant risk or actual injury will occur." (ECF No. 188, at 7.) The California REL is "exceptionally conservative" compared to estimated acute exposure limits in the literature. (*Id.* at 9.) It is based

⁶ Defendant also challenged Smith's reliance on Petersen's scenario one breathing zone model. (ECF No. 188, at 7.) This challenge fails because the court found Petersen's model met the threshold requirements for admissibility. (ECF No. 281.)

upon studies on pregnant mice and prolonged exposure. (*Id.* at 9–10.) To be even more conservative regulators “applied a cumulative uncertainty factor of 1,000.” (*Id.* at 10.) Defendant argues that these factors make the California REL an unreliable comparison for Smith’s risk assessment. (*Id.* at 11.)

The court would likely find Smith’s reliance on the conservative California REL unreliable were he offering an opinion about causation. Smith, however, only opined about the need for further study. Relying on a health-protective regulatory standard does not render such an opinion inadmissible. The fact finder can weigh whether the conservative nature of the California REL affects the accuracy of Smith’s opinion about the need for a health assessment.

Defendant challenges several aspects of Smith’s assessment of risk due to metals in the soil. Defendant challenges Smith’s tabulation of noncancer risk from metals listed in table 7 of Smith’s report.⁷ (ECF No. 188, at 16–17.) Defendant is particularly concerned with manganese, which Smith identified as responsible for 69 percent of the noncancer risk from ingestion of homegrown produce at receptor location 11. (Smith Rep. 20 tbl.7, ECF No. 190-1.) Defendant asserts that this data would not assist the trier of fact because manganese was not identified “as a metal of concern” in any claim in these cases. (ECF No. 188, at 16–17.) Plaintiffs assert that Smith included manganese in this table for the sake of completeness and because inclusion of all metals is typical in a screening risk analysis. (ECF No. 239, at 19.) Arsenic, however, “is the driving risk” identified by Smith. (*Id.*) Because the table lists a variety of metals and does not adequately explain how manganese and the other metals pose a health risk, the court concludes that the table could confuse the fact finder. Smith will be precluded from presenting this table to the fact finder.

7 Table 7 of Smith’s report (Relative Contribution of Various Metals to Risk at Receptor Location 11) is mislabeled as “table 6.” (Smith Rep. 20, ECF No. 190-1.) The text of Smith’s report refers to it as “table 7.” (*Id.* at 19.) The court will follow the text of the report and refer to it as “table 7.”

Smith used a “relative absorption factor” for arsenic of 100 percent—in effect assuming that all arsenic touching the skin would be absorbed. (*Id.* at 13.) Smith admitted that his use of the 100 percent relative absorption factor is “likely to be overly conservative.” (Smith Rebuttal Rep. 9, ECF No. 190-2.) Defendant also faults Smith for relying on outlier soil sampling results because most soil samples showed arsenic below the state screening level. (ECF No. 188, at 14–15, 17.)

These two arguments fault Smith for using a conservative approach. Since Smith is not opining about causation, but about the need for a health assessment, a regulatory risk assessment approach is appropriate. Risk assessment is intentionally conservative:

Risk assessment is not an exact science. It should be viewed as a useful framework to organize and synthesize information and to provide estimates on which policymaking can be based. ... Because of their use of appropriately prudent assumptions in areas of uncertainty and their use of default assumptions when there are limited data, risk assessments often intentionally encompass the upper range of possible risks.

Bernard D. Goldstein & Mary Sue Henifin, *Reference Guide on Toxicology*, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 633, 649–50 (3d ed. 2011). Smith’s regulatory approach may provide a useful framework for determining whether a health assessment study is an appropriate remedy.

Smith identified “a moderate statistical correlation” between black rain deposition and the health risk posed by exposure to particulate within the breathing zone. (Smith Rep. 21, 24 fig.4, ECF No. 190-1.) Smith testified, however, that he did not “have high confidence that that’s a real correlation.” (Smith Dep. 162:10–12, Apr. 24, 2013, ECF No. 190-3.) Instead, Smith found “an indication of potential risk,” which he felt justified a more thorough inquiry. (*Id.* at 170:23–171:8.) Because a risk assessment tends to encompass some uncertainty, the reservations expressed by Smith do not consign to the realm of inadmissibility his opinion with respect to a potential

correlation. Should Smith rely on this potential correlation, defendant can elicit testimony regarding his level of confidence.

With respect to whether a health assessment study is scientifically reasonable, Smith's opinion is sufficiently reliable to be admissible.

B. Defendant's Motions to Preclude the Testimony of Howarth

Howarth is a physician with extensive experience in occupational and environmental health. Howarth submitted expert reports about medical causation and damages issues with respect to eight individual plaintiffs in the *Price* case. In general, she opined that emissions of particulate matter from Bruce Mansfield exacerbated certain medical conditions—particularly asthma, but also allergies, bronchitis, heart disease, and chronic obstructive pulmonary disease—of those eight plaintiffs. Howarth also offered a general opinion, attached as “Appendix A” to each expert report, that a health effects study should be performed “to more completely characterize the full extent of contamination, the population at risk and the health impacts for which they are at risk.” (Howarth App. A, at 8, ECF No. 189-1.)

Defendant argues that Howarth's opinions about the exacerbation of existing conditions are unreliable and should be excluded for four reasons: (1) her dose and exposure analyses are unreliable; (2) she failed to perform an adequate differential diagnosis as to the cause of any of the plaintiffs' exacerbations; (3) she established no temporal link between alleged exposures and the onset of symptoms or exacerbation of existing conditions; and (4) her methodology cannot be tested or replicated. (ECF No. 186, at 2.) Defendant also argues that Howarth's opinion about plaintiffs' increased risk of cancer is unreliable and her opinion about the need for a health assessment does not help the finder of fact. Each of these arguments will be addressed.

1. Reliability of Dose and Exposure Analysis

Howarth's diagnosis focused on inhalation of fine particulate matter with a diameter of 2.5 micrometers or less (“PM_{2.5}”). (Howarth App. A, at 1, ECF No. 189-1.) Howarth opined that “medical evidence strongly demonstrates that these fine particu-

lates have detrimental health impacts, particularly to sensitive populations, including children, the elderly and those with underlying heart and lung compromise.” (*Id.*) In the individual diagnosis expert reports, Howarth opined that PM_{2.5} emitted by Bruce Mansfield exacerbated plaintiffs’ medical conditions. (*See, e.g.*, Hennen Diagnosis Rep. 5, ECF No. 189-4 (“The emissions from the Bruce Mansfield Plant have significantly increased the risk of harm to Brandon Hennen and are substantial factors in causing him harm.”).)

Defendant asserts that Howarth failed to set forth the dose of PM_{2.5} required to exacerbate asthma or cause the other deleterious health effects she diagnosed. (ECF No. 186, at 4.) Defendant argues that this failure renders her diagnoses unreliable because identifying a “‘dose-response relationship is a key element of reliability in toxic tort cases.’” (*Id.* at 3 (quoting *McClain v. Metabolife Int’l, Inc.*, 401 F.3d 1233, 1241 (11th Cir. 2005))). Defendant also argues that Howarth’s attempt to show the exposure of the plaintiffs to PM_{2.5} is fatally flawed because Howarth relied on the air dispersion modeling of Petersen and her exposure analysis is based on a hypothetical maximum scenario. (*Id.* at 5.) None of these arguments persuades the court that Howarth’s diagnoses should be precluded in their entirety. Speculative dose calculations, however, will be excluded as unreliable.

Howarth set forth an opinion regarding the dose required to cause adverse health effects. (Howarth App. A, at 4, ECF No. 189-1 (“Numerous studies have shown an increase incidence of respiratory, cardiovascular and mortality effects with PM 2.5 as low as 6–16 micrograms/cubic meter on average.”).) Howarth’s reliance on Petersen’s “scenario one” breathing zone air modeling is not problematic. The court found that the scenario one model met the threshold for admissibility. (ECF No. 281, at 16–18.)

Defendant points to Howarth’s diagnosis of James Bruce as an example of unrealistic hypothetical scenarios. Howarth determined the dose received by James Bruce by adding 98th percentile one-hour particulate concentrations from Petersen’s scenario one model (3.11–28.36 µm/m³) with 98th percentile measured particulate

concentrations from Beaver County (35–52 $\mu\text{m}/\text{m}^3$). (Bruce Diagnosis Rep. 4, ECF No. 189-6.) She then assumed that James Bruce would be exercising outside during “a time of air pollution excursion for both Beaver County and the Bruce Mansfield Plant,” which would increase his exposure by a factor of fifteen, for a total exposure of 1200 $\mu\text{m}/\text{m}^3$. (*Id.*) When questioned during her deposition, Howarth could not identify any particular time when those three factors coexisted: “[I]t is reasonable to believe that those things would coexist at the same time, but it is not possible to say that they coexisted at any given moment. I don’t have that data to know that for sure.” (Howarth Dep. 336:22–337:3, Feb. 18, 2013, ECF No. 189-14.)

The court finds this conclusion too speculative for two reasons. First, combining the predicted particulate concentrations from Bruce Mansfield with the measured concentrations at the Beaver County air monitoring station likely leads to double counting. Howarth recognized that Bruce Mansfield is “the major point source of PM 2.5 in the area.” (Bruce Diagnosis Rep. 5, ECF No. 189-6.) At least to some extent, particulate from Bruce Mansfield would be detected and included in the Beaver County data. (Hr’g Tr. 44:14–18, Feb. 4, 2014, ECF No. 277.) Second, assuming that plaintiffs engaged in outdoor physical exertion during periods when particulate concentrations were at 98th percentile levels, just 175 hours per year, is too speculative. James Bruce rode dirt bikes and played football as a child, but no evidence links these activities to a period of 98th percentile particulate concentration. Howarth’s exposure estimate of 1200 $\mu\text{m}/\text{m}^3$ is not based upon sufficient facts and data to be reliable. She will be precluded from testifying about that figure. Howarth’s entire opinion is not precluded on these bases because she concluded that the emissions from Bruce Mansfield alone are sufficient to make James Bruce symptomatic. (Bruce Diagnosis Rep. 4, ECF No. 189-6.) Howarth may offer her opinion about James Bruce’s diagnosis based upon that evidence.

With respect to six of the seven other plaintiffs she examined, Howarth similarly opined that the emissions from Bruce Mansfield alone are sufficient to cause

symptoms.⁸ (DC Diagnosis Rep. 3, ECF No. 189-2; Csomay Diagnosis Rep. 4, ECF No. 189-3; Hennen Diagnosis Rep. 4, ECF No. 189-4; Mayhue Diagnosis Rep. 4, ECF No. 189-8; Morris-Donner Diagnosis Rep. 3, ECF No. 189-9.) Howarth may offer her opinion about these diagnoses based upon that evidence. She may not opine that a specific plaintiff received an elevated dose due to outdoor exertion unless facts of record demonstrate that the individual engaged in such activity at a time when PM_{2.5} concentrations were at the 98th percentile level.

2. Adequacy of Differential Diagnosis

Differential diagnosis is a technique that involves ruling out alternative causes for symptoms “by a systematic comparison and contrasting of the clinical findings.” *Kannankeril v. Terminix Int’l, Inc.*, 128 F.3d 802, 807 (3d Cir. 1997) (internal quotation marks omitted). Differential diagnosis involves “the testing of a falsifiable hypothesis[,] ... has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results.” *Paoli II*, 35 F.3d at 758. It is “the basic method of internal medicine.” *Id.* at 755. Defendant argues that Howarth incorrectly applied the methodology because “where a defendant points to a plausible alternative cause and the doctor offers *no* explanation for why he or she has concluded that was not the sole cause, that doctor’s methodology is unreliable.” *Id.* at 759 n.27.

For each of the eight plaintiffs Howarth examined, defendant points to several plausible alternative causes. For example, Howarth opined that Brandon Hennen’s

⁸ The plaintiff who does not fall into this assessment is KB, a minor. Howarth assessed KB’s maximum exposure to PM_{2.5} from Bruce Mansfield as 0.57–5.57 µm/m³. (KB Diagnosis Rep. 3, ECF No. 189-7.) This level is below the 6–16 µm/m³ Howarth identified as causing increased respiratory, cardiovascular, and mortality effects. (Howarth App. A., at 4, ECF No. 189-1.) Howarth may not opine that Bruce Mansfield exacerbated KB’s medical conditions unless facts of record demonstrate that KB engaged in outdoor activity that would increase exposure at a time when PM_{2.5} concentrations from Bruce Mansfield were at the 98th percentile level.

asthma was exacerbated by particulate from Bruce Mansfield. (Hennen Diagnosis Rep. 5, ECF No. 189-4) Defendant points to alternative causes for his asthma exacerbations, such as allergies, exposure to chalk dust, diesel fumes, and nasal polyps.⁹ (ECF No. 186, at 13–16.)

The court finds that Howarth performed an adequate differential diagnoses. She took medical histories, conducted physical examinations, and applied exposures estimated from air modeling data. Howarth ruled out causes that she deemed implausible. (*See, e.g.*, Mayhue Diagnosis Rep. 4, ECF No. 189-8 (ruling out a genetic basis for plaintiff’s heart disease because plaintiff’s brother, who did not live near Bruce Mansfield, did not have any heart disease).) Howarth did not rule out all other causes, and she admitted that it is not possible to do so. (Howarth Rebuttal Rep. 5, ECF No. 189-10 (“In most asthmatics, exacerbations are triggered by a combination of factors. It is not possible to know the sum total of exacerbating factors that coexist at any given time for any given patient nor is it possible to predict the timing when enough factors are present to cause serious asthma exacerbation.”).)

Plaintiffs, however, do not assert that pollution from Bruce Mansfield was the sole cause of plaintiffs’ medical conditions, merely that it was a “substantial cause.” (ECF No. 243, at 9 (citing *Burton v. Johns-Manville Corp.*, 613 F. Supp. 91 (W.D. Pa.

⁹ Defendant points to the following alternative causes and inconsistencies in Howarth’s differential diagnosis with respect to the other individual plaintiffs. James Bruce: allergies, stress, and dirt-bike riding (ECF No. 168, at 19); KB: family history, allergies, smoke from burning garbage, and infections (*id.* at 20–21); DC: dog allergies, feather pillow allergies, and sought treatment on days when air quality was above average (*id.* at 20–21); Renee Hunter: allergies, aerosols, photography chemicals, cold weather, automobile exhaust, and cigarette use (*id.* at 23–25); Michele Morris-Donner: allergies, cigarette use, and worsening of symptoms after moving further away from Bruce Mansfield (*id.* at 26–27); Joseph Csomay: cigarette use, weight gain, and work-related exposure to asbestos and silica (*id.* at 27–28); Mark Mayhue: cigarette use, family history, high cholesterol, and seasonal nature of symptoms (*id.* at 30–31). Because Howarth used the same kind of differential diagnosis for each of the eight plaintiffs she examined and because defendant raises similar challenges to each opinion, the court collectively addresses the challenges.

1985)).¹⁰ A defendant can be liable even when there are concurring causes. *See, e.g., Shamnoski v. PG Energy*, 765 A.2d 297, 304 (Pa. Super. Ct. 2000) (“If a negligent act and an act of God combine to produce damages that would not have occurred absent negligence, and the negligent act was a substantial factor in causing the injury, liability attaches.”). Howarth’s differential diagnosis is sufficiently reliable and helpful in this context.

Defendant’s reliance on *Minner v. American Mortgage & Guarantee Co.*, 791 A.2d 826 (Del. Super. Ct. 2000), in which Howarth participated as an expert, is misplaced. In that case, the court excluded Howarth’s expert testimony that the defendant’s building caused plaintiffs’ chronic fatigue syndrome and fibromyalgia because “she did not follow a careful scientific methodology to exclude other possible causes” of plaintiffs’ illnesses and because chronic fatigue syndrome and fibromyalgia have no known cause. *Id.* at 860. The court, however, permitted the jury to hear Howarth’s opinion with respect to occupational asthma and other conditions which have known causes. *Id.* at 860–61. In the instant case, inhalation of PM_{2.5} is known to cause respiratory and cardiovascular problems, particularly in sensitive populations. (Howarth App. A, at 1, ECF No. 189-1.)

Bland v. Verizon Wireless, (VAW) L.L.C., 538 F.3d 893 (8th Cir. 2008), is also distinguishable. The Court of Appeals for the Eighth Circuit concluded that “the district court did not abuse its considerable discretion” in excluding a medical expert who opined that exposure to Freon caused the plaintiff’s exercise-induced asthma. *Id.* at 898. The court concluded that the expert’s differential diagnosis failed because “the cause of exercise-induced asthma in the majority of cases is unknown.” *Id.* at 897. The expert could not therefore opine that exposure to Freon was “the most probable

10 Recently, courts have disfavored the use of “substantial factor,” preferring “factual cause.” *See Gorman v. Costello*, 929 A.2d 1208, 1213 & n.7 (Pa. Super. Ct. 2007); 2 PA. SUGGESTED STANDARD CIV. JURY INSTRUCTIONS § 13.00 subcommittee note (4th ed. 2011) (“‘Substantial factor’ or ‘substantial contributing factor’ is the epitome of vagueness . . .”).

cause” of the exercise-induced asthma. *Id.* (internal quotation marks omitted). The expert also did not investigate or analyze the plaintiff’s “home or other environments” to determine other possible causes of the plaintiff’s asthma. *Id.* at 898. In this case, Howarth took a medical history of each plaintiff and analyzed factors in their homes and elsewhere that could contribute to their symptoms. She did not opine that pollution from Bruce Mansfield was the most probable cause of plaintiffs’ illnesses—she opined that “[t]he emissions from the Bruce Mansfield Plant have significantly increased the risk of harm to [plaintiffs] and are substantial factors in causing [them] harm.” (*E.g.*, Hennen Diagnosis Rep. 5, ECF No. 189-4.)

Howarth’s differential diagnoses are sufficiently reliable to be submitted to the jury. This is not a case where the expert offered “no explanation” addressing alternative causes. *Paoli II*, 35 F.3d at 759 n.27. The jury can weigh Howarth’s diagnosis opinions in light of the evidence of alternative causes of plaintiffs’ medical conditions. *See Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 202 (4th Cir. 2001) (“A medical expert’s opinion based upon differential diagnosis normally should not be excluded because the expert has failed to rule out every possible alternative cause of a plaintiff’s illness. In such cases, the alternative causes suggested by a defendant normally affect the weight that the jury should give the expert’s testimony and not the admissibility of that testimony.” (citation omitted)); *Kannankeril*, 128 F.3d at 808 (reversing district court for excluding expert’s differential diagnosis where the record was “devoid” of any alternative diagnosis that the expert “ignored or failed to consider”).

3. *Lack of Temporal Link Between Symptoms and Pollution*

Defendant asserts that Howarth did not find any temporal link between plaintiffs’ symptoms and pollution from Bruce Mansfield. (ECF No. 186, at 31–32 (citing *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 158 (3d Cir. 1999).) In *Heller*, the plaintiffs alleged harm from volatile organic compounds (“VOCs”) emitted by carpeting installed in their home. One of the plaintiffs’ experts “relied extremely

heavily on the temporal relationship between the installation of the carpet” and plaintiffs’ illness. *Heller*, 167 F.3d at 159. The plaintiffs’ symptoms, however, did not begin until one or two weeks after the carpet was installed, and the symptoms persisted after the carpet was removed, a temporal relationship that “was questionable at best and exculpatory at worst.” *Id.* at 157, 158. The court concluded that “[w]ithout either scientific studies pointing to VOCs of the type and amount detected as the culprit *or* a reliable temporal relationship, [the expert] was left with no valid means for concluding that” the carpet caused the plaintiffs’ illness. *Id.* at 159.

Howarth did not rely on a temporal relationship in reaching her conclusions with respect to most plaintiffs.¹¹ Defendant’s contention that “even where the plaintiff’s expert’s methodology was reliable, where temporality was lacking the court found his conclusion did not ‘fit’ with the data and methodology” lacks merit and appears to be based upon a flawed reading of *Heller*. (ECF No. 168, at 32.) There is no requirement that a strong temporal link exist where an expert relies on other evidence. In this case, the alleged exposure is cumulative and occurred over many years—the entire lives of some plaintiffs—and the lack of a strong temporal connection is not surprising under this theory.

4. *Ability of Methodology to be Tested or Replicated*

Defendant asserts that Howarth’s methodology is unreliable because it cannot be tested or replicated and amounts to nothing more than *ipse dixit*. (*Id.* at 32.) Defendant points to Howarth’s testimony that she considered factors she deemed relevant and information she found most accurate in order to “make a judgment as to what the complex nature of exposures that someone has experienced” demonstrates. (Howarth Dep. 71:9–16, 75:5–10, 83:4–14, Feb. 18, 2013, ECF No. 189-12.)

¹¹ Howarth did note some “temporal factors” in her diagnosis of Brandon Hennen. (ECF No. 243, at 19.)

Howarth's methodology is no less testable or repeatable than any other proper differential diagnosis, a methodology widely accepted by the medical profession and courts. *Paoli II*, 35 F.3d at 758. Another physician could conduct physical examinations of plaintiffs, gather their medical histories, review the literature about the health effects of particulate matter, and review the breathing zone modeling. To the extent that Howarth made judgment calls about the relevance of certain factors and information, those judgments are simply inherent in the differential diagnosis process. *Id.* (“[D]ifferential diagnosis ... involves far more elements of judgment than does a scientific study attempting to test a more general scientific proposition. While an important aspect of assessing scientific validity (and therefore evidentiary reliability) is the ability of other scientists to test or retest a proponent's theory, differential diagnosis involves assessing causation with respect to a particular individual. This merely makes it a different type of science than science designed to produce general theories; it does not make it unreliable science.”).

5. *Reliability of Opinion About Increased Risk of Cancer*

Howarth opined that white and black rain from Bruce Mansfield contributed to increased levels of arsenic on properties near the plant and an increased cancer risk to residents of those properties. (Howarth App. A, at 8, ECF No. 189-1.) Howarth's individual diagnosis reports also mention the increased cancer risk. (E.g., Bruce Diagnosis Rep. 4, ECF No. 189-6.) Defendant asserts that Howarth's opinion that Bruce Mansfield caused an increased risk of cancer for the eight *Price* plaintiffs is unreliable. (ECF No. 186, at 33.) Plaintiffs note that Howarth did not offer the opinions about increased risk of cancer in support of the *Price* plaintiffs' individual tort claims for monetary damages. (ECF No. 243, at 38.) The opinion about cancer risk “relates to the request that the Defendant fund a health effect study,” which is at issue in the *Patrick* case (*Id.*; see Compl. ¶ 80, ECF No. 1.) Howarth will therefore be precluded from giving any opinion about increased risk of cancer to the plaintiffs in

the *Price* case. The admissibility of her opinions about the need for a health assessment study in the *Patrick* case is addressed below.

6. *Fit of Opinion About Need for Health Assessment Study*

Howarth offered an opinion, similar to Smith's, that a health assessment is needed to quantify the health risks posed by Bruce Mansfield. (Howarth App. A, at 7, ECF No. 189-1.) Defendant asserts that "[a]lthough Plaintiffs have not framed their claim as one for medical monitoring, the case law related to medical monitoring provides the most relevant standard for assessing their claim."¹² (ECF No. 186, at 37.) Defendant argues that Howarth "has not provided sufficient testimony to meet any of the elements set forth in *Redland Soccer*." (*Id.* at 38.) Therefore, defendant argues, Howarth's opinion about the need for a health assessment is not helpful to the finder of fact and should be excluded on "fit" grounds. (*Id.* at 39.)

Even considering the elements in *Redland Soccer* as modified, the court is unpersuaded by defendant's arguments. The inquiry with respect to fit under *Daubert* is not whether expert testimony is sufficient to meet any of the modified elements; rather, the fit inquiry "goes primarily to relevance." *Daubert*, 509 U.S. at 591; *Paoli II*, 35 F.3d at 745 & n.13. Howarth opined that "[a]n extensive body of scientific evidence shows that exposure to particle pollution causes premature death and is linked to a variety of significant health problems." (Howarth App. A, at 1, ECF No. 189-1.) This opinion is relevant to element two, "a proven hazardous substance." *Redland Soccer*, 696 A.2d at 145. Howarth opined that "environmental testing performed by Gary Brown, P.E. has revealed levels of arsenic that are greater than PA statewide health standards in soils." (Howarth App. A, at 6, ECF No. 189-1.) This opinion is relevant to element one, "exposure greater than normal background levels." *Redland Soccer*, 696

12 Plaintiffs contest this point. (ECF No. 243, at 40.) For the purpose of deciding this *Daubert* motion, the court considers the standard for a health assessment substantially similar to the elements of a medical monitoring claim as set forth in *Redland Soccer*. See *supra* p. 7.

A.2d at 145. Howarth opined that “[t]he information gathered to date regarding the health risks posed by the historical and current emissions of the Bruce Mansfield Plant strongly indicates the need for additional assessment.” (Howarth App. A, at 7, ECF No. 189-1.) This opinion is relevant to element seven, the health assessment “is reasonably necessary according to contemporary scientific principles.” *Redland Soccer*, 696 A.2d at 146.

Howarth’s opinions are relevant and connected to contested issues in the case. Whether her testimony is sufficient to meet plaintiffs’ burden on the merits of those elements is not properly before the court on a *Daubert* motion. Howarth’s opinions about the need for a health assessment will not be excluded on fit grounds.¹³

IV. Conclusion

Defendant’s motions to preclude the expert testimony of Smith will be granted in part and denied in part. Due to the potential for confusion, if the health assessment claim is to be determined by a jury, Smith may not offer his opinion unless an appropriate limiting instruction is given. Smith may not present table 7 of his report to the fact finder, and he will be precluded from relying on high levels of manganese to support his opinion. The motions will be denied in all other respects.

Defendant’s motions to preclude the expert testimony of Howarth will be granted in part and denied in part. Howarth may not give an opinion based upon combining predicted particulate from Bruce Mansfield and measured particulate from the Beaver County air monitoring station. Howarth also may not opine that outside exertion increased a plaintiff’s exposure unless record facts show that that plaintiff engaged in such activity at a time when particulate concentrations were at the 98th percentile level. Howarth may give her opinion about adverse health effects due to

¹³ Contingent on whether imposing the cost of a health assessment or health effects study is question for the court or a jury, the court may hear Howarth’s testimony outside the presence of the jury or give a limiting instruction, as appropriate. See *supra* footnote 5.

particulate emissions from Bruce Mansfield, except that Howarth may not opine that the emissions from Bruce Mansfield alone are sufficient to cause KB's symptoms unless facts of record demonstrate that KB engaged in outdoor activity that would increase her exposure at a time when PM_{2.5} concentrations from Bruce Mansfield were at the 98th percentile level. Howard is precluded from giving an opinion about the increased risk of cancer in the *Price* case. The motions will be denied in all other respects.

Appropriate orders will be entered.

Dated: March 31, 2014

/s/ Joy Flowers Conti

Joy Flowers Conti

Chief United States District Judge